UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,265	09/05/2001	Keiko Yamasaki	2001-1026A	3583

513 7590 01/20/2004

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,265	YAMASAKI ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time, request for RCE, and amendment, all filed 11/19/2003.

Claims 1-6 have been canceled, and claims 7-9 have been added. Claims 7-9 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,363 ('363) in view of US 5,725,874 ('874).

US '363 teaches a composition for topical application to the skin comprising two or more active agents to achieve therapeutic effect or multiple therapeutic effects or both (abstract; col.2, lines 53-60; col.7, lines 57-59; col.8, lines 24-26). Non-steroidal anti-inflammatory agent can be administered in conjunction with a local anesthetic agent to provide reduction in pain by means of both the analgesic effect and the anesthetic effect of such agents (col.8, lines 26-31). Analgesics include bufexamac, felbinac, flurbiprofen, indomethacin, ketoprofen, and suprofen (col.10, lines 5-34). Anesthetics include benzocaine, dibucaine, lidocaine, procaine, and tetracaine (col.10, line 45 till col.11, line 3; col.30, lines 22-26). The concentration of the active agents can be varied independently from 1-40% of the total weight of the composition in order to achieve the

desired therapeutic effect (col.32, lines 45-48, 60-62). The composition further comprising water-soluble polymer, cross-linking agent, water, and polyhydric alcohol (col.2, lines 47-51; col.3, lines 17, 47, 59; col.5, lines 41-44; col.7, lines 38-40). The composition included in a delivery device as reservoir that has a backing layer (col. 3, lines 39-41; col.41, lines 13-25).

Although the reference disclosed the generic teaching of including a cross-linking agent in the composition, the reference does not teach specifically the aluminum compounds as the cross-linking agent.

US '874 teaches a percutaneous preparation that has long stability, releasability, percutaneous absorbability and safety for the skin (col.3, lines 40-43). The preparation comprising 0.01 to 20% of a drug; water-soluble polymer; water; humectants selected from polyhydric alcohol including polyethylene glycol, propylene glycol, butylenes glycol, glycerol, and sorbitol; and cross linking agents such as aluminum compounds (abstract; col.3, lines 28-30, 66-67; col.4, lines 1-2, 8-10, 14-20). The dosage form of the preparation can be in the form of reserve patches that have a support (abstract; col.3, line 37; col.4, line 47). The drug to be delivered in the percutaneous preparation includes anti-inflammatory agents selected from diclofenac, ketoprofen, flurbiprofen, felbinac, and indomethacin; and local anesthetic such as lidocaine, benzocaine, and procaine (col.2, lines 60-63; col.3, lines 11-12; col.4, line 66 till col.5, line 2).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the transdermal patch comprising combination of analgesic and local anesthetic in the composition that comprises cross-linking agent as

disclosed by US '363, and replace the cross-linking agent by the aluminum compounds as disclosed by US '874, motivated by the of any of US '874 that the percutaneous preparation that has the aluminum compounds has long stability, releasability, percutaneous absorbability and safety for the skin, with reasonable expectation of having a stable percutaneous composition that relieves pain for prolonged period of time.

5. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,686,112 ('112) in view of US '874.

US '112 disclosed a transdermal therapeutic system for topical application of systemically acting pharmaceutical substances (abstract). To improve efficacy and tolerability of a transdermal systemic pain or rheumatism treatment, analgesics and local anesthetics are delivered in single dosage topical pharmaceutical form including non-steroidal anti-inflammatory analgesics such as indomethacin and diclofenac, and local anesthetics such as lidocaine and benzocaine (col.3, lines 1-9; col.6, lines 16-18).

The reference does not teach a specific preparation for the transdermal therapeutic system and doses of the drugs as disclosed by applicants.

US '874 teaches a percutaneous preparation that has long stability, releasability, percutaneous absorbability and safety for the skin (col.3, lines 40-43). The preparation comprising 0.01 to 20% of a drug; water-soluble polymer; water; humectants selected from polyhydric alcohol including polyethylene glycol, propylene glycol, butylenes glycol, glycerol, and sorbitol; and cross linking agents such as aluminum compounds (abstract;

col.3, lines 28-30, 66-67; col.4, lines 1-2, 8-10, 14-20). The dosage form of the preparation can be in the form of reserve patches that have a support (abstract; col.3, line 37; col.4, line 47). The drug to be delivered in the percutaneous preparation includes anti-inflammatory agents selected from diclofenac, ketoprofen, flurbiprofen, felbinac, and indomethacin; and local anesthetic such as lidocaine, benzocaine, and procaine (col.2, lines 60-63; col.3, lines 11-12; col.4, line 66 till col.5, line 2).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the transdermal patch comprising combination of analgesic and local anesthetic to relief pain as disclosed by US '112, and deliver the combination of the drugs in the percutaneous preparation disclosed by US '874, motivated by the of any of US '874 that the percutaneous preparation that has water-soluble polymer, water, humectants and cross-linking agent has long stability, releasability, percutaneous absorbability and safety for the skin, with reasonable expectation of having a stable percutaneous composition that relieves pain for prolonged period of time.

Response to Arguments

6. Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048.

The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali